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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/478,598	01/06/2000	A. Gururaj Rao	5718-16A	1892

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/478,598

Applicant(s)

RAO ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 April 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 54-83,97-107 and 115-118.Claim(s) withdrawn from consideration: 84-96 and 108-114.

8. ☒ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☒ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: Attached Interview Summary (Paper No. 12)

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action (Final Rejection, Paper No. 10 mailed on January 2, 2002), Applicants filed an after-final amendment (Paper No. 11). Claims 54-118 are pending in the instant application. Claims 84-96 and 108-114 remain withdrawn from further consideration as non-elected inventions. Claims 54-83, 97-107, and 115-118 will be examined herein.

### ***Status of After-Final Amendment***

2. The after-final amendment (Paper No. 11) filed on April 9, 2002 has been entered to correct typographical errors in the claims and to align the specification with the new drawings filed (see below).

### ***Priority***

3. The instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 08/988,015 filed on December 10, 1997 as requested in the first lines of the specification.

### ***Drawings***

4. New drawings were filed on April 9, 2002 along with an amendment to the specification to correct the brief description of the drawings. The labeling of Figure 1 and Figure 1A is unacceptable. Said labeling should be Figures 1A and 1B. New drawings are required along with appropriate amendment to the specification. Also, a complete set of amended drawings must be filed for consideration by the Draftsman.

***Maintained – Claim Rejections – 35 U.S.C. § 112***

5. Previous rejection of Claims 54-83, 97-107, and 115-118 under 35 U.S.C. § 112, first paragraph, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive.

Applicants argue that the claims are fully described and enabled by the specification using the Wands analysis. Applicants note the working example in the specification as well as the state of the art as noted in scientific publications satisfy that the claims are, in fact, enabled. The Examiner disagrees. The instant claims would require undue experimentation because, as the Examiner previously noted, the experimentation is not routine. That is to say that the experimentation required would be *wholly unpredictable*.

Applicants argue that the claims emphasize that the protein product has at least substantially retained the native conformation of the protein. This argument is not found persuasive because this limitation is not clearly set forth in the claims.

Applicants continually argue that the experimentation is routine, particularly in the declaration of Inventor Sleister under 35 U.S.C. § 1.132. The Examiner disagrees. While the immunological assays provided may recognize gross changes in the conformation, the instant claims read on *any* conformational change which cannot be predictably probed by *any* antibody or conformation-recognizing-agent that recognizes the native state of a protein. The Examiner agrees that antibody-recognizing assays are routine – it is their probe of the conformation that lacks enablement in the claimed methods. The breadth of the instant claims exceeds the enablement of the specification combined with the state of the art.

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*Conclusion*


6. No claims are allowed in the application. The finality of Paper No. 10, mailed on January 2, 2002, is maintained. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to the final action (Paper No. 10) was noted previously in Paper No. 10 and is reiterated here.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
PONNATHAPUACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER

KMK  
May 7, 2002